

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: 3M ESPE AG
Street: ESPE Platz
ZIP-Code, City: D-82229 Seefeld
Federal State: Bavaria
Country: Germany
Establishment Registration Number 9611385
Official Correspondent: Dr. Andreas Petermann,
..... Senior Specialist Regulatory Affairs
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Date: November 2, 2004

Name of Device

Proprietary Name: Hermes Bond 2
Classification Name: Resin tooth bonding agent
Common Name: Dental Adhesive

Predicate Devices

Adper Prompt L-Pop by 3M ESPE K 020946
RelyX Unicem by 3M ESPE K 020256
Protemp 3 Garant by 3M K 033022

Description for the Premarket Notification

Hermes Bond 2 is classified as Resin Tooth Bonding Agent (21 C.F.R. § 872.3200) because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restorative material.

Like Adper Prompt L-Pop, 3M ESPE's well-known and well-established resin bonding agent, Hermes Bond 2 offers the advantages of a simplified bonding procedure, eliminating the need for a separate etching step. Thus it reduces both possible errors during application and post-operative sensitivity. Additionally, it saves the dentist valuable chair time. Being based on methacrylate chemistry itself, Hermes Bond 2 is well suited for bonding methacrylate composites. The compatibility to silorane based composites is ensured by the formulation of Hermes Bond 2 which has especially been optimized for this purpose. In fact, the bond strength obtained for Hermes/Hermes Bond 2 is comparable to that of Adper Prompt L-Pop with conventional methacrylate composites.

Hermes Bond 2 is also intended to be used as a bonding mediator for fissure sealing as is Adper Prompt L-Pop.

Like Adper Prompt L-Pop, Hermes Bond 2 will be available in single dose applicators and in a two-vial version.

To provide evidence for safety biocompatibility testing was carried out. The results show that Hermes Bond 2 is a safe device.

The comparison for chemistry, performance data and indications for use shows that Hermes Bond 2 is substantially equivalent to the predicate devices.

In summary, it can be concluded that safety and effectiveness requirements for Hermes Bond 2 are completely met.



JAN 10 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Andreas Petermann
Manager, U.S. Regulatory Affairs
3M ESPE AG
ESPE Platz
Seefeld, D-82229
GERMANY

Re: K043043
Trade/Device Name: Hermes Bond 2
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 02, 2004
Received: December 08, 2004

Dear Dr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043043

Device Name: Hermes Bond 2

Indications For Use: Bonding between dentin/enamel and silorane based composite filling materials

Bonding between dentin/enamel and methacrylate based composite filling materials

Bonding mediator for fissure sealing

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043043

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